DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 22 1994

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Re: Lipidil®
Docket No. 94E-0104



The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,739,101, filed by Fournier Innovation et Synergie under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lipidil®, the human drug product claimed by the patent.

The total length of the regulatory review period for Lipidil® is 4,501 days. Of this time, 1,003 days occurred during the testing phase and 3,498 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 6, 1981.

   The applicant claims August 16, 1981, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 6, 1981, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: June 4, 1984.

   FDA has verified the applicant's claim that the new drug application (NDA) for Lipidil® (NDA 19-304) was initially submitted on June 4, 1984.

3. The date the application was approved: December 31, 1993.

   FDA has verified the applicant's claim that NDA 19-304 was approved on December 31, 1993.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Dr. Max Fogiel
61 Ethel Road West
Piscataway, New Jersey 08854